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Post-Vaccination Adverse Reactions Follow-up

The important elements for a post-vaccination follow-up plan are three. First is safety of the patients and the non-vaccinated staff. Second is active surveillance for adverse reactions associated with the vaccination. And, third is accurate and prompt reporting to public health authorities.

Safety should always take priority. The post-vaccination safety efforts revolve around preventing inadvertent inoculation of others with the vaccinia virus (that is, the virus contained in the smallpox vaccine). The key component of this protection is disciplined hand washing. The vaccinia virus produces its protective antibodies while present in the superficial layer of the skin. After introduction of the virus into the epidermis at vaccination, the virus multiplies and produces a lesion that matures through stages: papule, vesicle, pustule, and then a scab. All of these lesions contain live virus in them. Preventing the virus transmission to other sites of the vaccinee and other people in the hospital is the principle mission of the hospital. The post-vaccination process as described and recommended by the Advisory Committee on Immunization Practices (ACIP) consists of checking the bandage and the vaccination site before the beginning of each shift for all the vaccinated hospital personnel. The bandage will consist of a gauze pad covered with a semi-permeable covering. If the bandage is showing evidence of saturation of fluid from the lesion or from water, or the bandage is not sticking, it should be removed and replaced by a previously vaccinated person (a nurse or other healthcare professional). The worker then should wear a long sleeve shirt and refrain from scratching or handling the lesion or bandage. All personnel who handle the bandage or the lesion should wash their hands thoroughly with soap and water before moving on to other tasks. The care taker should be wearing gloves and change them between patients. This process should continue until the scab falls off (approximately 21 days).

Active surveillance for adverse events begins with the inspection of the vaccination site described above. The site inspector will question the patient about signs and symptoms associated with the vaccination. Usually, these will be present by day 7. On day 7 (allowed range between day 6 through day 8), the inspector will examine the site and decide whether the reaction is a “major reaction” or an “equivocal reaction”. Information on how to interpret vaccine reactions is contained in other parts of this manual, and training on primary vaccination site reading will be provided at the upcoming training sessions. *A major reaction is required to record a “take.”* Anything other than a major reaction is non-take or an equivocal reaction and requires revaccination to ensure a “take.” The “take” response will have to be reported on-line by the institution in the HAWK-IMMUNIZATION database (instructions will follow) and recorded at the bottom of the “Patient Medical History and Consent Form,” page 3. It is imperative that all vaccinees receive follow-up and “take” responses are recorded.

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As recommended by the CDC and emphasized by a recent report from the Institute of Medicine, all vaccinees will be actively followed until the scab falls off. In order to accomplish this, the institution which will have people observing the vaccination site will need to ask the vaccinee to complete a short list of questions on days 7, 14, and 21 using the Kansas Smallpox Vaccine Reaction Surveillance Form (found in this binder). The vaccinee will complete the form while at the inspection station and return the form to someone at the station before departing. The completed forms will be returned after each collection (3 times) to the Bureau of Epidemiology and Disease Prevention following procedures that will be described at a later date. When an individual indicates in the survey that they visited a physician during the previous seven days for causes related to the smallpox vaccination, the Bureau of Epidemiology and Disease Prevention staff will contact the physician to gather more information. All major adverse reactions reported to KDHE will also be entered in the computerized information system. The intent of this active surveillance is to record and analyze all minor or major adverse reactions.

Should the inspector be unsure of how to interpret a take, or in the presence of significant adverse reactions, the vaccinee should be referred to the pre-identified physician in the institution responsible for triaging adverse reactions. Upon decision of the type of reaction or adverse event, the physician will report his/her assessment back to the inspector at the facility. In the presence of a possible major adverse reaction, the physician should report the findings immediately to the KDHE Senior Medical Epidemiologist via the Epidemiology "hot-line" at 1-877-427-7317, 24 hours a day. The Senior Medical Epidemiologist will consult with the attending physician and assist the attending in deciding the disposition of the patient. The Center for Disease Control and Prevention (CDC) also has a Clinical Information Line at 1-877-554-4625 available for consultation. Major adverse events should also be reported to the federal Vaccine Adverse Event Reporting System (VAERS) (by calling 1-800-822-7967 or electronically at http://secure.vaers.org/vaersdataentry.cfm). The option to report adverse events to VAERS is available to anyone, including patient, family member, health care provider, institution, or public health agency.

The attached diagram is included to provide a quick overview of the system showing linkages and important phone numbers.

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